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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,179	12/12/2003	Wendelin Frick	DEAV2002-0086 US NP	1661

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EXAMINER

OWENS, AMELIA A

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,179	<b>Applicant(s)</b> FRICK ET AL.	
	<b>Examiner</b> Amelia A. Owens	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/10/2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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# **DETAILED ACTION**

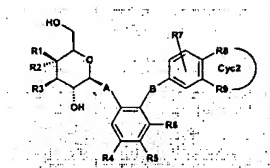
1. Claims 1-13 are pending.

## ***Election/Restrictions***

2. Applicant's election without traverse of Group I, compounds in the reply filed on July 10, 2006 is acknowledged.

The election is considered without traverse as no arguments traversing the restriction accompanied the election.

Compounds of the formula



A is oxygen; B is CH<sub>2</sub>; R1/R2/R3 are as defined; R7 is H; R8 is H, OH, Et, Cl, OCF<sub>3</sub>, Ome; R9 is H; R4 is H, Me, Ome, OH; R5 is H, F, Ome; R6 is H, OH; R8/R9 are independent -- have been examined.

Claims 1-7 read on the elected invention and have been examined to the extent they encompass the above elected subject matter.

Claims 8-13 are held withdrawn as being directed to nonelected invention, 37 CFR 1.142(B).

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds outlined in above paragraph 2, does not reasonably provide enablement for the invention as now claimed. The specification does not enable any physician skilled in the art of medicine, to make the invention commensurate in scope with these claims. "The [eight] factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art and the breadth of the claims", *In re Rainer*, 146 USPQ 218 (1965); *In re Colianni*, 195 USPQ 150, *Ex parte Formal*, 230 USPQ 546.

**The nature of the invention:** The nature of the invention is compounds that are used to treat diabetes.

**The state of the prior art and predictability:** The state of the prior art is that chemical reactions are unpredictable. There is no absolute predictability even in view of the seemingly high level of skill in the art. It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable given myriad of compounds produced and that chemical reactions are involved. For example variable A – is composed of a combination of electron withdrawing and electron donating groups. The oxygen is electron donating while the NH is electron withdrawing. Further, R8/R9 may form a cycle2 group or be independent; cycle1 group may be 3-7 members, unsaturated, partially saturated or saturated containing no heteroatom or (1) heteroatom selected from O,N,and S. The properties, bonding, structure of each of these ring systems is different. For example, (1) 6-membered heterocycles differ from 5-membered heterocycles in that the heteroatom contributes 2-electrons to the 6pi system, whereas

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6-membered heteroatoms contribute only 1-electron to this system; (2) pyridine (6-membered N heterocycle) is very resistant to electrophilic aromatic substitution; (3) furan is more reactive than benzene toward electrophilic substitution; (4) the compound contains chiral carbons which effects the reactants. These are a few of the factors that influence reaction mechanism, reaction conditions – and contribute to the unpredictability of preparing the claimed compounds.

USP 6515117 that teaches C-aryl glycoside compounds is noted. The compounds are structurally removed from the claimed compounds.

Also, the state of the prior art is that it involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities (i.e. what compounds can treat which specific disease). A slight change in the structure of the compound would drastically change its biological activity in vitro. In the in vivo system, the degree of unpredictability multiplies in view of the complexity of the physiological conditions.

**Guidance and working examples:** Some compounds according to the invention have been made. It is clear that reaction conditions, reactants, reaction mechanism are not disclosed for the myriad of compounds claimed. The reactants, reaction conditions, reaction mechanism are essential to the claimed invention.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable". Applicant should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. If you (the public) find that it works, I claim it, is not a proper basis of patentability.

MPEP §2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here and undue experimentation will be required to practice Applicants' invention.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Amelia A. Owens  
Primary Examiner  
Art Unit 1625